IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

Inventors:	Carsten Momma, Andreas Becker, Robert Schmiedl, and Bernd Heublien
Serial No.:	10/630,355
Filed:	July 30, 2003
For:	ENDOVASCULAR IMPLANT FOR THE INJECTION OF AN ACTIVE SUBSTANCE INTO THE MEDIA OF A BLOOD VESSEL
Art Unit:	3738
Examiner:	Brian E. Pellegrino

BRIEF ON APPEAL

To: Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal under 37 C.F.R. §1.191 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the final rejection of claims 1, 3-15, and 26-29 in the above-identified patent application. One (1) copy of Appellant's Brief on Appeal is filed herewith, and the requisite filing fee under 37 C.F.R. §1.17(f) is also paid herewith.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest in the present application is Biotronik Mess- und Therapiegeraete GmbH & Co., by assignment from inventors Carsten Momma, Andreas Becker, Robert Schmiedl, and Bernd Heublien. The assignment is recorded in the United States Patent and Trademark Office at Reel 014916, Frame 0391.

II. RELATED APPEALS AND INTERFERENCES

There has been no previous appeals in this application.

There have been no interferences or related litigation.

III. STATUS OF CLAIMS

The status of the claims in this application is:

1. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are 18 pending claims in this application, numbered 1, 3-15, and 26-29.

In the Office Action of March 4, 2005, the Examiner stated that the application contained claims directed to three patentably distinct inventions: Invention I: Claims 1-29, classified in class 623, subclass 1.42; Invention II: Claims 30 and 31, classified in class 427, subclass 534; Invention III: claim 32, classified in class 430, subclass 281.1. The Examiner also indicated that the application contained claims directed to six patentably distinct species as follows:

Species A: Fig. 2	Species D: Fig. 5
Species B: Fig. 3	Species E: Fig. 6
Species C: Fig. 4	Species F: Fig. 7.

The Appellant elected Invention I, Species A with traverse. Claims 16-25 and 30-31 were withdrawn from consideration.

In the Amendment mailed March 29, 2006, the Appellant cancelled claims 2 and 30-32.

With regard to the claims on appeal, claims 1, 3-11, 14, 15 and 26-29 are generic, and claims 12 and 13 are directed to Species A (Fig. 2).

2. STATUS OF ALL OF THE CLAIMS

A. Claims canceled: 2, and 30-32.

B. Claims withdrawn from consideration but not canceled: 16-25.

C. Claims pending: Claims 1, 3-29.

D. Claims allowed: NONE.

E. Claims rejected: 1, 3-15, 26-29.

3. CLAIMS ON APPEAL

The claims on appeal are claims 1, 3-15, 26-29.

IV. STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the Final Action of November 16, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

All citations to the specification refer to the specification that was filed on July 30, 2003. FIGS. 1 and 2 of the present application are reproduced below.

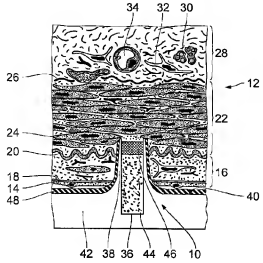

Fig. 1

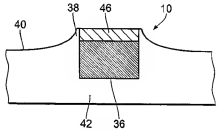

Fig. 2

Independent claim 1 is directed to an endovascular implant for applying an active substance **36** into the media **22** of a blood vessel **12**. (Paragraph 0012, Fig. 1). The implant comprises a base body **42** which has a plurality of microdevices **10** for applying the active substance **36**, disposed at least in a portion of the surface **40** of the implant, the microdevices **10** being adapted to face towards the blood vessel **12**. (Paragraphs 0033-0040, particularly 0036-0038, Abstract, Fig.1). Each microdevice **10** includes at least one microcannula **38** which projects from the implant surface **40** by between 100 and about 400 μm such that, when the implant bears in surface contact against a wall **14** of the blood vessel **12**, the microcannula **38** penetrates into the media **22** of the blood vessel **12**. (Paragraphs 0014 and 0036, Fig. 1). At least

one deposit of the active substance **36** is in communication with at least one microcannula **10**. (Paragraph 0039, Fig. 1).

Claim 3 recites that the at least one microcannula **10** projects from the implant surface **40** by between about 150 and about 300 μm and claim 4 recites that the at least one microcannula **10** projects from the implant surface **40** by between about 180 and about 250 μm. Claim 5 recites that the at least one microcannula **10** has a diameter of 20-200 μm. (Paragraph 0036).

Claims 6 and 7 recite that the microdevices **10** are component parts of the base body **42**. (Paragraph 0016). Claims 8 and 9 recite that the microdevices **10** are applied to the base body **42** using hybrid technology. (Paragraph 0017). Claims 10 and 11 recite that the at least one active substance **36** is liberated only after penetration of the at least one microcannula **38** into the media **22** of the blood vessel **12**. (Paragraph 0018).

Claims 12 and 13 recite that the implant includes a cover layer **46** of a biodegradable material that closes the plurality of microdevices **10** after the at least one active substance **44** has been introduced into the active substance deposit **36**. (Paragraphs 0018 and 0039). Claims 14 and 15 recite that the at least one active substance **44** is embedded in a biodegradable drug carrier. (Paragraph 0018).

Claims 16 and 17 recite that a plurality of active substances are introduced into the active substance deposit such that stepwise liberation of the active substances occurs. Claims 18 and 19 recite that a plurality of layers of biodegradable drug carriers with embedded active substances are introduced into the active substance deposit and are successively broken down. Claims 20 and 21 recite the presence of at least one separating layer of a biodegradable material, each of which is successively broken down and which separates the various active substances from each other. (Paragraph 0019).

Claim 22 recites that regions of the surface of the implant that are outside the microdevice are covered with a layer of a biodegradable material. (Paragraph 0020).

Claim 23 depends from claim 22 and recites that this layer of biodegradable material terminates flush in a peripheral direction at a tip of the microcannulae of the microdevice or completely covers the microdevice and a breakdown behaviour on the part of the layer is matched with the liberation behaviour of the active substance, such that liberation of the active substance begins only after complete breakdown of the layer. Claim 24 recites the presence of self-expanding structures which promote progressive penetration of the microcannulae into the vessel wall. Claim 25 recites that the layer of biodegradable material comprises hyaluronic acid polymers with different degradation kinetics. (Paragraph 0021).

Claim 26 recites that the implant is a stent and claim 27 recites that the stent is adapted for use as a coronary stent. (Paragraph 0022).

Claim 28 recites that the base body is formed at least in portion-wise manner from a biodegradable material. Claim 29 recites that the base body is formed, at least in portion-wise manner, from a magnesium alloy. (Paragraph 0023).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 3-12, and 26-29 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 6,254,632 to Wu et al.

2. Whether claims 14 and 15 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 6,254,632 to Wu et al. in view of U.S. Pat. No. 6,287,628 to Hossainy et al.

VII. ARGUMENTS

1. The Rejection of Record

Currently, claims 1 and 3-29 are pending in the present application. Claims 16-25 have been withdrawn from consideration. Claims 1, 3-15 and 26-29 stand rejected.

In the Office Action of November 16, 2006, the Examiner rejected claims 1, 3-13 and 26-29 as being obvious in view of U.S. Pat. No. 6,254,632 to Wu et al. (hereinafter "Wu"). The Examiner maintains that Wu discloses "a stent having a base body with a plurality (col. 8, lines 50-56) of microdevices 200 that project from the implant surface to form a microcannula 218 on the outer surface to engage a vessel wall (col. 6, lines 13-17)." The Examiner also maintained that the recitation in the claims that the microcannulae penetrate into the media of the blood vessel was given no weight. The Examiner further inferred the length of the microcannulae of Wu from the description of cover surrounding the stent (Wu, column 9, lines 17-19).

The Examiner also rejected claims 14 and 15 as obvious over Wu in view of U.S. Pat. No. 6,287,628 to Hossainy et al. (hereinafter "Hossainy"). The Examiner asserts that Wu teaches the elements of these claims except the use of a biodegrable drug carrier to hold the active substance, and that Hossainy provides such a teaching.

Figs. 2A-2C of Wu are reproduced below.

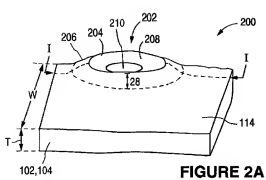

FIGURE 2A

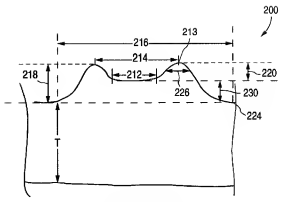

FIGURE 2C

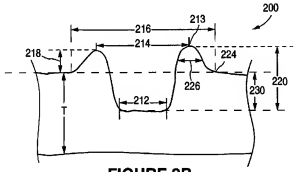

FIGURE 2B

2. Claims Rejections under 35 U.S.C. §103(a)

A claimed invention is unpatentable under 35 U.S.C. §103 if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103 (1994); *Graham v. John Deere Co.,* 383 U.S. 1, 14 (1966); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ , No. 04-1350, *slip op.* at 2 (2007). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *KSR Int'l* at 2.

A. The Examiner has the Burden to Establish a Prima Facie Case of Obviousness

The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. MPEP §2142. If the Examiner does not establish a *prima facie* case, the applicant is under no obligation to respond. MPEP §2142. To reach a proper determination under §103, the Examiner must step backward in time and into the shoes of the hypothetical person of ordinary skill in the art when the invention was unknown and just before it was made. MPEP §2142. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP §2142.

B. Criteria/Analysis the Examiner Must Meet to Establish a Prima Facie Case of Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met by the Examiner.

1. Motivation to Combine

First, there must be some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet,* 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998).

Under Federal Circuit precedent, the showing of a motivation to combine or modify prior art must be clear and particular, and broad conclusory statements about the teachings of one or more references, standing alone, are not "evidence." *In re Dembiczak,* 175 F.3d 994, 1000, 50

U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Further, the showing of obviousness "requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references." *Dembiczak*, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617.

Ultimately, this first criterion provides "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis." *Dembiczak*, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617. This is because "most if not all inventions arise from a combination of old elements," potentially allowing every element of the claimed invention to be found in the prior art. *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000). Solely identifying each element of the claimed invention in the prior art is not enough to defeat patentability of the invention as a whole, unless there existed a teaching, suggestion, or motivation to combine the prior art references. *Kotzab*, 217 F.3d at 1370, 55 U.S.P.Q.2d at 1316-17. Otherwise, "rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *Rouffet,* 149 F.3d at 1357, 47 U.S.P.Q.2d at 1457. Thus, the initial burden is on the examiner to establish the existence of a teaching, suggestion, or motivation to combine the prior art references at the time the invention was made.

Recently, the Supreme Court rejected the use of the "teaching, suggestion, or motivation" test (TSM test) as a "rigid and mandatory (formula)" that "limits the obviousness inquiry" in favor of viewing the TSM test as a "general principle" and a "helpful insight." *KSR Int'l Co.* at

15. However, the Supreme Court also reiterated, that an invention is not shown to be obvious "merely by demonstrasting that each of its elements was, independently, known in the prior art." *KSR Int'l Co.* at 14. Furthermore, the Supreme Court did not eliminate the motivation to combine from an obviousness analysis. To the contrary, the Court indicated, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does." *KSR Int'l* at 15. Therefore, while the Supreme Court's decision in ***KSR International Co.*** expands the possible sources of motivation to combine, it does not eliminate the requirement.

2. Reasonable Expectation of Success

Second, there must be a reasonable expectation of success. Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (Bd. Pat. App. & Inter. 1986). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

3. Prior Art Must Teach or Suggest All the Claim Limitations.

The third and final requirement for a finding of obviousness requires the prior art reference (or references when combined) to teach or suggest all the claim limitations. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (COCA 1970).

C. Argument Regarding Claim 1 And All Pending Claims As Dependent Upon Claim 1

1. U.S. Patent No. 6,254,652 to Wu Does Not Teach Or Suggest All Elements Of Claim 1

The present invention is directed to an endovascular implant adapted to deliver and active substance to the media of a blood vessel in which it is placed. This is accomplished by microstructures designed to penetrate past the blood vessel and into the media of the blood vessel. This represents an improvement over the prior art, which provides active substances that are applied only to the intima of a blood vessel (See Paragraph 0010). Diffusion from the prior implants into the blood vessel wall however, is impeded by plaque, calcification or thickened vessel wall layers. (Paragraph 0010).

The Examiner maintains that Wu discloses "a stent having a base body with a plurality (col. 8, lines 50-56) of microdevices 200 that project from the implant surface to form a microcannula 218 on the outer surface to engage a vessel wall (col. 6, lines 13-17)." The Examiner also maintains that the description of the cover of the stent of Wu could also support the interpretation of the structures of Wu having the same length as the microcannulae of the present invention. However, the Examiner's inference is only one of several possible inferences and the use of the thickness of a cover on Wu's stent to infer the length of the microcannulae is contradicted by the explicit statements of Wu regarding the length of the microdevices. As previously stated in the response filed September 8, 2006 (page 8), Wu clearly discloses a lip height 218 of 10-80 μm (Wu, col. 11, lines 65-67, Figs. 2B-2C).

While Wu provides a stent that includes structures that allow delivery of a therapeutic substance directly to the wall of the vessel, Wu does not teach or suggest microcannulae that

penetrate into the vessel wall to the media of the vessel. Wu only teaches that the microcannulae, or "craters" as termed by Wu, "can be used to deliver therapeutic substances from the stent directly to the lumen wall..." (column 2, lines 60-62). As shown in Fig. 1 and as explained in the accompanying description in paragraph 0034 of the present application, the wall of an artery contains three layers: the intima 16 which is bounded by an inner elastic membrane 20 and a basal lamina 18 underlying endothelium cells 14; the media 22; and the adventitia 28. Wu merely provides that the protruding structures or craters "engage the lumen of the passageway ... to help prevent the stent from slipping out of the treatment site." (Wu, Column 6, lines 15-17). As stated in the response of February 27, 2006, a "lumen" is actually an inner open space or cavity, in this case, of the blood vessel. Therefore, by using this terminology, Wu can only mean that the craters 200 contact ("engage") the wall of the blood vessel at its inner surface. Wu does not teach or suggest structures that penetrate into the vessel past the endothelium, the basal lamina, and the inner elastic membrane and allow delivery of such substances directly into the media. Additionally, Wu's terminology (i.e. "craters") for these structures further indicates that Wu does not intend or envision these structures as delivering an active substance to the media of a blood vessel as in the present invention. Rather, the structures of Wu are merely intended to engage and secure the stent to a vessel or to a cover for the stent.

The Examiner contends that the Applicant's assertion that Wu's stent would not penetrate to the media, "is an improper statement because the Applicant has arbitrarily selected a dimension less than what Applicant's claims recite." This is clearly not true. The specification goes to great lengths to explain the benefits and close tolerances necessary to deliver an active substance to the media of a blood vessel. (See paragraphs 0014 and 0036). On the other hand, the disclosure of the length of the lip height 218 of Wu, 10-80 μm is also clear. No other lip

height is disclosed by Wu. In fact, it is the Examiner's selection one one possible inference of the lip height of Wu, taken from the description of the cover of Wu, that has been arbitrarily selected to match the claimed microcannulae length. Therefore, the Examiner's finding of a possible suggestion of the claimed invention in Wu is based on hindsight. The Examiner also cites *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-1383 (Fed Cir 2003) as supporting the rejection. However, *Peterson* involved the obviousness of a range that was encompassed by a larger prior disclosed range, not a range adjacent to a prior disclosed range as in the present application.

2. There Is No Motivation To Modify The Stent Of Wu To Arrive At The Present Invention.

One of ordinary skill in the art would not have found any suggestion or motivation to modify the length of the "craters" of Wu to 100-400 μm, or to any length other than that disclosed by Wu, 10-80 μm. The Examiner states that the intended use of the microcannulae in the claims carries no weight absent a distinguishing structure. However, such a structure is explicitly provided by the claims by indicating the length necessary to perform the function. Contrary to the Examiner's assertions, the Applicants have provided a distinct advantage of the claimed microcannula length ranges, namely, to deliver therapeutic products directly into the media of blood vessels, not just to the interior surface of the blood vessels. Wu does not provide any teaching or suggestion that such delivery is desirable or possible. Neither has the Examiner provided any indication that such a motivation to modify Wu would be found by one of ordinary skill in the art in the knowledge generally available to one of skill in the art. In fact, as discussed in the specification, and as well known in the art, insult to the walls of a blood vessel, including insult occurring as a result of stent placement, can cause restenosis. (See Paragraph 0035)

Therefore, one of skill in the art would not have found any motivation in Wu or in the knowledge generally available to one of ordinary skill in the art, to modify an implant such as a stent provided by Wu to actually penetrates the walls of a blood vessel. Furthermore, some claims provide further elements designed to overcome any residual tendency to cause restenosis from penetration of the blood vessel wall, particularly claims 24 and 25 (see Paragraph 0021).

3. There Is No Reasonable Expectation Of Success In Modifying The Length Of The Microstructures Of Wu

One of ordinary skill in the art would likelwsie have no expectation of success in modifying Wu. As stated above, restenosis was a well recognized problem associated with stent usage. It was also recognized that injury to the blood vessel wall could cause restenosis. Therefore, one of ordinary skill in the art would not have had a reasonable expectation of success in treating patients successfully with a stent that included structures that actually penetrated the blood vessel wall prior to the present invention.

D. Argument Regarding Claims 14 and 15

The Examiner asserts that Wu fails to disclose the use of a biodegrable drug carrier to hold the active substance, and that Hossainy provides such a teaching. However, neither Wu nor Hossainy teach or suggest microcannulae as recited in the claims, as provided above. The arguments provided with regard to Wu are repeated herein with regard to claims 14 and 15. The examiner has provided no allegation that Hossainy provides a teaching or suggestion of such microcannulae.

E. Conclusion

The Applicants respectfully assert that all the pending claims are allowable for at least the following reasons: and this claim and all those pending claims which depend from it patentably distinguish over Wu.

1. Wu does not teach or suggest all the elements of claim 1, from which the remaining pending claims depend.
2. There is no motivation to modify the microstructures of Wu to provide microcannulae that deliver an active substance to the media of a blood vessel.
3. There is no reasonable expectation of success in the microstructures of Wu to provide microcannulae that deliver an active substance to the media of a blood vessel

In accordance with the foregoing, the Applicants respectfully request reversal of the Examiner and allowance of all claims.

Respectfully submitted,

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VIII. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

1. An endovascular implant for applying an active substance into the media of a blood vessel, said implant comprising:

a base body which has a plurality of microdevices for applying the active substance disposed at least in portion-wise manner at a surface of the implant adapted for facing towards the blood vessel, wherein each said microdevice includes at least one microcannula which projects from the implant surface by between 100 and about 400 μm such that, when the implant bears in surface contact against a wall of the blood vessel, the microcannula penetrates into the media of the blood vessel, and

at least one deposit of the active substance which is in communication with at least one said microcannula.

3. The implant of claim 2, wherein:

the at least one microcannula projects from the implant surface by between about 150 and about 300 μm.

4. The implant of claim 3, wherein:

the at least one microcannula projects from the implant surface by between about 180 and about 250 μm.

5. The implant of claim 2, wherein:

the at least one microcannula are of a diameter of 20 - 200 μm.

6. The implant of claim 1, wherein:

the microdevices are component parts of the base body.

7. The implant of claim 5, wherein:

the microdevices are component parts of the base body.

8. The implant of claim 5, wherein:
the microdevices are applied to the base body using hybrid technology.

9. The implant of claim 1, wherein:
the microdevices are applied to the base body using hybrid technology.

10. The implant of claim 5, wherein:
a liberation behaviour in respect of the at least one active substance to be deposited is so established that the at least one active substance is liberated only after penetration of the at least one microcannula into the media of the blood vessel.

11. The implant of claim 1, wherein:
the at least one active substance to be deposited is liberated only after penetration of the at least one microcannula into the media of the blood vessel.

12. The implant of claim 10, wherein:
a cover layer of a biodegradable material closes the plurality of microdevices after the at least one active substance has been introduced into the active substance deposit.

13. The implant of claim 11, wherein:
a cover layer of a biodegradable material closes the plurality of microdevices after the at least one active substance has been introduced into the active substance deposit.

14. The implant of claim 10, wherein:
the at least one active substance is embedded in a biodegradable drug carrier.

15. The implant of claim 11, wherein:
the at least one active substance is embedded in a biodegradable drug carrier.

16. (withdrawn) The implant of claim 10, wherein:

a plurality of active substances are introduced into the active substance deposit such that stepwise liberation of the active substances occurs.

17. (withdrawn) The implant of claim 11, wherein:

a plurality of active substances are introduced into the active substance deposit such that stepwise liberation of the active substances occurs.

18. (withdrawn) The implant of claim 16, wherein:

a plurality of layers of biodegradable drug carriers with embedded active substances are introduced into the active substance deposit and are successively broken down.

19. (withdrawn) The implant of claim 17, wherein:

a plurality of layers of biodegradable drug carriers with embedded active substances are introduced into the active substance deposit and are successively broken down.

20. (withdrawn) The implant of claim 16, comprising:

at least one separating layer of a biodegradable material, each of which is successively broken down and which separates the various active substances from each other.

21. (withdrawn) The implant of claim 17, comprising:

at least one separating layer of a biodegradable material, each of which is successively broken down and which separates the various active substances from each other.

22. (withdrawn) The implant of claim 1, wherein:

regions of the surface of the implant that are outside the microdevice are covered with a layer of a biodegradable material.

23. (withdrawn) The implant of claim 22, wherein:

the layer of biodegradable material terminates flush in a peripheral direction at a tip of the microcannulae of the microdevice or completely covers the microdevice and

a breakdown behaviour on the part of the layer is matched with the liberation behaviour of the active substance, such that liberation of the active substance begins only after complete breakdown of the layer.

24. (withdrawn) The implant of claim 22, comprising:

self-expanding structures which promote progressive penetration of the microcannulae into the vessel wall.

25. (withdrawn) The implant of claim 22, wherein:

the layer of biodegradable material comprises hyaluronic acid polymers with different degradation kinetics.

26. (original) The implant of claim 1, wherein:

the implant is a stent.

27. The implant of claim 26, wherein:

the stent is adapted for use as a coronary stent.

28. The implant of claim 26, wherein:

the base body is formed at least in portion-wise manner from a biodegradable material.

29. The implant of claim 28, wherein:

the base body is formed, at least in portion-wise manner, from a -magnesium alloy.

IX. EVIDENCE APPENDIX

EXHIBIT 1
Office Action dated November 16, 2006

EXHIBIT 2

U.S. Patent No. 6,254, 632 to Wu

Submitted by Applicant in an Information Disclosure Statement filed January 21, 2004.

First Reviewed by the Examiner June 6, 2005.

First Cited by the Examiner in an Office Action June 8, 2005.

EXHIBIT 3

U.S. Patent No. 6,287,628 to Hossainy

Submitted by Applicant in an Information Disclosure Statement filed January 21, 2004.

First Reviewed by the Examiner June 6, 2005.

First Cited by the Examiner in an Office Action June 8, 2005.

X. RELATED PROCEEDINGS APPENDIX

NONE